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United States Senate

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WASHINGTON, DC 20510-6000

202-224-2035

TTY/TDD 202-224-2587

July 7, 2005

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The Honorable Mike Johanns
Secretary of Agriculture
U.S. Department of Agriculture
200-A Jamie L. Whitten Building
Washington, D.C. 20250

Dear Secretary Johanns:

This letter is to follow up on our telephone conversation last week about the Department of Agriculture's testing and surveillance program for bovine spongiform encephalopathy (BSE) in the wake of the announcement on June 24 that BSE had been confirmed in the U.S. from a beef animal first tested in November 2004. As you clearly recognize, confidence in USDA's anti-BSE measures are absolutely critical to maintaining consumer confidence in beef, protecting U.S. cattle herds and our beef industry against BSE, and reopening markets that are still closed to U.S. beef exports after more than a year and a half of negotiations.

To be sure, virtually all of the most crucial actions and decisions that have recently come to light – as well as the basic formulation of USDA's anti-BSE policies – occurred before you became Secretary. The changes you have directed are critically needed, and I commend you for them. While it is certainly important now to look ahead, it is also critical to get to the bottom of how the recently disclosed problems came about and to ensure that similar lapses do not occur in the future. Based on what you and other USDA officials have said publicly, it is my understanding that the following problems and deficiencies within USDA are being cured immediately: the lack of a clear protocol for confirmatory testing in the case of conflicting results; the long delay in confirmatory testing, which unnecessarily caused a second negative hit to the cattle market; the public representation that a sample is BSE-negative even though a test (albeit experimental) suggested it was positive; the lack of paperwork filed with the IHC test in November; and the mislabeling and improper storage and handling of samples.

On a related point, I want to make clear that USDA's Office of Inspector General is to be commended in this matter. Without the prompting of the OIG, we still would not know that the brain sample in question tests BSE-positive. Simply put, accurate and factual knowledge is not the enemy in our efforts against BSE – it is vital. Whatever problems there may have been in communication, the primary responsibility for communicating to the Secretary about the decision to conduct further testing was from the ARS or APHIS personnel at the field level up through their chain of command. In any case, it was ARS and APHIS personnel who ultimately carried out the further testing. This case provides no basis whatsoever for any actions by USDA officials

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that would seek to curtail or limit the ability of the OIG to carry out its statutory authority and responsibilities. For example, it would clearly be improper interference with the OIG if field level USDA personnel, in whatever agency, are led to believe that cooperation with the OIG or following OIG recommendations henceforth has to be cleared by the Secretary.

Even with the positive actions that the Department has recently announced, there are still too many unanswered questions and apparent problems in USDA's BSE testing and surveillance program to instill the level of confidence that is so crucial to assure consumers and reopen closed markets.

Early in 2004, USDA announced that it would seek to test 268,500 cattle from the so-called "high-risk" population. USDA has touted the fact it has now tested over 388,000 of these high-risk cattle and found only one positive animal, and that does seem to be a strong effort – at least on its face. But that number by itself is meaningless unless the testing of that number of cattle is part of a system of testing that is demonstrably valid, using accepted statistical principles, to draw conclusions about the assumed prevalence level of BSE in U.S. cattle. Indeed, the USDA Inspector General has stated there are "inherent problems" with how USDA has defined, obtained and tested this class of "high-risk" cattle. For example, it is undisputed that the cattle tested are not a truly random statistical sample since the testing is entirely voluntary.

At the same time it announced its plans for testing high-risk cattle, USDA also announced that it would test 20,000 clinically normal aged cattle. (There is a good scientific basis for testing this class of cattle, since in other countries many cases of BSE have been found in clinically normal aged cattle.) In a letter to Secretary Ann Veneman on May 10, 2004, I raised a number of questions about the plans for testing 20,000 clinically normal aged cattle, including whether that would be a sufficient number to reach statistically valid conclusions. I suggested that either more animals in this category be tested or that testing resources should be focused on a more carefully defined class of these clinically normal aged cattle, such as those born near or before the U.S. ruminant-to-ruminant feed ban was adopted. Under Secretary Bill Hawks responded, in a letter dated June 30, 2004, that "...USDA makes no statistical claims for these numbers. These animals will be sampled in accordance with the recommendation of the international review team." In fact, in August 2004, an audit report on USDA's BSE surveillance program from the Inspector General determined that testing for BSE in a population of 20,000 clinically normal aged cattle was statistically insignificant. USDA officials then told the OIG that the 20,000 animals were not being tested to determine statistically the maximum BSE prevalence rates in normal cattle, but rather "to deter producers who might send potentially infected cattle into the normal slaughter process."

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I go into this detail about USDA's announced plan to test 20,000 clinically normal aged cattle because its handling is emblematic of how USDA's shifting BSE policies and explanations of them undermine USDA's credibility and thus threaten consumer confidence and the reopening of lost export markets. When USDA announced the plan to test 20,000 clinically normal aged cattle, it was with the clear impression that testing these cattle would add an extra measure of assurance as to the absence or extremely low prevalence of BSE – above and beyond the results from testing the 268,500 “high-risk” cattle. But USDA had to abandon that line once it was untenable to suggest that testing only 20,000 clinically normal aged cattle would provide any statistically valid conclusions. USDA's deterrence justification for testing these 20,000 cattle has all the marks of an after-the-fact rationalization, not the least of which is its facial illogicality. (E.g., how would a producer know cattle are potentially infected if they are clinically normal?) Yet the real surprise is that over a year later, USDA has not tested *any* clinically normal aged cattle and it presently has no plans to do so, despite its announcements and representations to the public, the OIG and me that it would test 20,000 of them. In other words, the point at issue was whether 20,000 would be a sufficient number of this type of cattle to test – and so USDA just quietly decided not to test any.

As I stated publicly following your June 24 announcement, “I stress that consumers should have no misgivings about eating beef based on this test result.” But certainly there is a limit to how much of its own errors, inconsistencies and lack of transparency USDA can reasonably expect consumers to abide and still have confidence in the safety of beef. Now that a domestic BSE case has been confirmed, it is even more urgent that USDA provide publicly a full analysis of the results of its BSE testing and surveillance program, including any adjustments to the statistical model. This analysis must include a justification of the validity of the methods used according to accepted statistical principles along with the conclusions that can be drawn, and at what level of confidence, concerning the incidence of BSE in U.S. cattle. Of course, all indications are that it is exceedingly low, but at this point USDA has not issued a recent statistical analysis to demonstrate the fact. If there are, as the OIG and others with expertise have suggested, statistical problems in BSE testing and surveillance – such as in the randomness of sampling – USDA must explain how any deficiencies will be corrected.

These points are probably even more critical with respect to the efforts to reopen U.S. beef export markets closed since December 2003. I certainly am not suggesting Japan and Korea are behaving reasonably, but we do not control that. We do, however, have responsibility for our own USDA. In that regard, it seems USDA has failed thus far to grasp what is needed to succeed in negotiations to reopen these markets. An example is the October 23, 2004 announcement by the administration of a framework for resumption of beef trade with Japan, with a USDA official stating it would be just “a matter of weeks.” This rushed and premature announcement gave a misleading picture of a done deal. Eight and a half months later, Japan's market is still closed to U.S. beef. The recent revelations of problems in USDA's BSE testing and surveillance program can only further complicate and impede what were already very difficult negotiations.

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On December 30, 2003, not long after the BSE discovery in Washington State, then Secretary Veneman announced she would "expedite" the development of the technology architecture to implement a national animal identification system. Yet, after a year and a half, USDA still has not even identified all of the farms and ranches with livestock and poultry in the United States, which is the first of a long series of steps to implementing the system. I'm not suggesting USDA should move forward at a reckless pace and implement a flawed or unnecessarily burdensome system. But I am concerned that at USDA's current pace, countries that have already implemented animal identification, such as Canada, will have their trade restored before the United States. Until a national animal identification system is fully implemented in this country, our nation will continue to have difficulty in restoring foreign markets.

Thank you for your attention to the concerns and questions I have raised. I look forward to your response and to working with you to strengthen USDA's anti-BSE program in order to ensure consumer confidence and reopen our beef export markets.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Tom Harkin", with a stylized flourish at the end.

Tom Harkin
Ranking Democratic Member